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Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

DEPARTMENT OF HEALTH & HUMAN SERVICES

1141 Central Parkway
Cincinnati, OH 45202-1097

June 25, 1998

WARNING LETTER
CIN-WL-98-279

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Raymond L. Christensen, President
Westlake Laboratories, Inc.
24700 Center Ridge Road
Cleveland, OH 44145

Dear Mr. Christensen:

This letter is in reference to your firm's marketing and distribution of the product, Bevitamel. Promotional literature (labeling) titled "Product Information" makes therapeutic claims for Bevitamel in the treatment of "depression" and "seasonal affective disorders(SAD)". Bevitamel is advertised in the 1998 "Physicians' Desk Reference"(PDR) for use in "depression, seasonal affective disorders(SAD)" and "treatment of sleep disorders." Bevitamel is advertised on the Internet with additional claims for "coronary heart disease, and elevated serum cholesterol." These claims cause Bevitamel to be a drug [§ 201(g) of the Federal Food Drug, and Cosmetic Act (the Act)].

Bevitamel is a "new drug" [§ 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [§ 505(a) of the Act].

This drug is also misbranded because its labeling fails to bear adequate directions for the conditions for which it is offered [§ 502(f)(1) of the Act] and its labeling is false and misleading. The labeling suggests that this product is safe and effective for its intended use, when in fact, this has not been established [§ 502(a) of the Act].

The promotional literature titled "Product Information" contains information on a number of additional products marketed by your firm. Labeling for these products contains disease claims. These disease claims may cause the products to be unapproved new drugs and to be misbranded.

FDA has recently published a proposed rule which outlines the Agency's position on what types of statements are considered structure/function versus what statements are considered to be disease claims. In addition, this document specifically states that publication titles or other references which refer to disease intended uses represent disease claims. Many of the disease claims included in "Product Information" are provided through publication titles.

Further, we are aware of the following additional products marketed by your firm with objectionable claims in their labeling:

Bona-Bacillus	gas and stomach cramps, reducing the toxicity of intestinal Candida infections
Coenzyme Q-10	cardiovascular disease, heart failure, allergies, respiratory disease, cognitive function deficits, obesity, diabetes
GFS-2000	cancer prevention
Glutanac	detoxification of...carcinogens, enhance selectivity of chemotherapy, cancer prevention
Nutrisure(RX)	reduce incidence of chronic disease, atherosclerotic heart disease, cardiovascular disease, tumor progression, cancer prevention
Nutrisure-Cu(RX)	reduce incidence of chronic disease, atherosclerotic heart disease, cardiovascular disease, tumor progression, cancer prevention
Nutrisure OTC	reduce incidence of chronic disease, atherosclerotic heart disease, cardiovascular disease, tumor progression, cancer prevention
Pantethine	elevated cholesterol, arthritis, chronic alcoholism, peptic ulcers, hypertension, cardiovascular disease, hyperlipoproteinemia
Phosphatidyl-Serine	Alzheimer's disease, brain damage due to disease, drug and alcohol use, and pollution
Total-E	atherosclerotic heart disease, cancer prevention, tumor progression, cardiovascular disease, Parkinson disease
Ultra Carotenoids	anticancer properties, atherosclerotic heart disease, cancer prevention, stroke, cardiovascular disease
Ultra GI	cancer prevention

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Ultra Lipoic Forte	supporting treatment for diabetes, especially neurologic complications, atherosclerosis, cerebral damage, heavy metal poisoning, radiation damage, cancer prevention, mitochondrial cytopathy, diabetic peripheral and cardiac autonomic neuropathy
Uro-Pro	prevent and correct Benign Prostate Hypertrophy(BPH) and enlarged prostate, prostatic hyperplasia, cancer prevention

We note that promotional sites on the Internet for both Westlake and King James Medical Lab contain disease claim statements for Bevitamel. Such promotions can serve to establish the intended use of a product and cause it to be a drug.

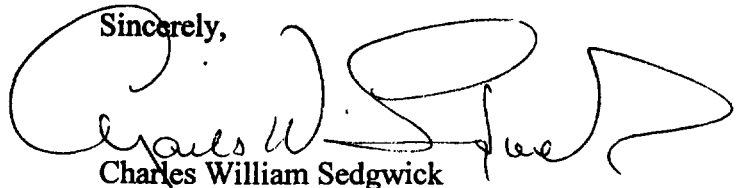
This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the U.S. Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202-1097, to the attention of, Evelyn D. Forney Compliance Officer. Any question regarding this letter may be directed to Ms. Forney at telephone no. (513) 684-3501 extension 163.

Sincerely,



Charles William Sedgwick
Acting District Director
Cincinnati District